Complete Summary

GUIDELINE TITLE

Parathyroid hormone.

BIBLIOGRAPHIC SOURCE(S)

Elder G. Parathyroid hormone. Nephrology 2006 Apr;11(S1):S209-16.

Elder G. Parathyroid hormone. Westmead NSW (Australia): CARI - Caring for Australasians with Renal Impairment; 2006 Jan. 17 p. [35 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Chronic kidney disease
- End-stage kidney disease

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine

Nephrology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To explore the evidence on intact-parathyroid hormone levels in patients with chronic kidney disease and end-stage kidney disease

TARGET POPULATION

Adults and children with chronic kidney disease and end-stage kidney disease

INTERVENTIONS AND PRACTICES CONSIDERED

Monitoring of intact-parathyroid hormone levels for non-invasive assessment of renal osteodystrophy

- Low bone turnover
- High bone turnover

MAJOR OUTCOMES CONSIDERED

- Low bone turnover disease
- High bone turnover disease
- Morbidity
- Cardiovascular mortality
- Mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched: MeSH terms and text words for parathyroid hormone were combined with MeSH terms and text words for chronic kidney disease and renal replacement therapy. These were combined with MeSH terms and text words for bone disease, bone biopsy, bone histomorphometry, bone mineral density, bone turnover markers, biochemical markers and cardiovascular disease. The searches were carried out in Medline, Embase and the Cochrane Controlled Trial Register (in May 2005) and abstracts of scientific meetings were searched for randomized controlled trials.

Latest search date: May 2005.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Recommendations of Others. Recommendations regarding parathyroid hormone levels in patients with chronic kidney disease from the following groups were discussed: Kidney Disease Outcomes Quality Initiative, UK Renal Association, Canadian Society of Nephrology, European Best Practice Guidelines, and Kidney Disease Improving Global Outcomes.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence (I–IV) can be found at the end of the "Major Recommendations" field.

Guidelines

a. For patients on dialysis, levels of intact-parathyroid hormone (iPTH) that are within or below the normal range of the assay are generally indicative of low bone turnover and levels of iPTH that are greater than 2 to 3 times the upper normal range of the assay are generally indicative of high bone turnover. (Level l evidence)
b. For the non-invasive assessment of renal osteodystrophy, assays for iPTH and parathyroid hormone (PTH)(1 to 84) have similar diagnostic value. (Level ll evidence)

Suggestions for Clinical Care

(Suggestions are based on Level III and IV sources)

- For patients on dialysis, normal bone turnover is generally associated with levels of iPTH that are 1 to 3 times the upper normal range of the assay. For bone, the suggested target iPTH is from 1 to 3 times the upper normal range of the assay, with most opinion favouring 2 to 3 times. (Opinion)
- Markedly elevated levels of iPTH are associated with an increased risk of cardiovascular mortality and sudden death. Values that are > 7 times the upper normal range of the iPTH assay should generally be avoided. (Level lll evidence)
- When iPTH levels are below 7 times the assay upper range, therapies to achieve bone targets for PTH that compromise target levels of serum calcium,

phosphate or the calcium x phosphate product should be used with caution. (Opinion)

- PTH levels determined using assays for iPTH and PTH (1 to 84) correlate closely. However, iPTH assays vary in their detection of C-terminal PTH fragments and values may differ between assays (Level lll evidence). PTH (1 to 84) assays that measure the full length polypeptide are reported to be more directly comparable. (Level lll evidence) For comparison of PTH values in multicentre clinical trials, the use of a PTH (1 to 84) assay may be preferable. (Opinion)
- In assessing bone turnover, the value of the PTH (1 to 84)/non-PTH (1 to 84) ratio remains uncertain. (Opinion)
- PTH levels should be checked monthly when changes of therapy that may influence PTH are introduced and 2 to 3 monthly in other patients on dialysis. (Opinion)
- PTH levels may respond rapidly to interventions that influence calcium, phosphate and vitamin D levels but bone and cardiovascular responses may take months to years. Bone and cardiovascular outcomes are more likely to correlate with PTH trends or averaged values than with isolated PTH values. (Opinion)

Definitions:

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate management of intact-parathyroid hormone levels in patients with chronic kidney disease and end-stage kidney disease
- Appropriate non-invasive assessment of renal osteodystrophy in patients with chronic kidney disease and end-stage kidney disease

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Jan

GUIDELINE DEVELOPER(S)

Caring for Australasians with Renal Impairment - Disease Specific Society

SOURCE(S) OF FUNDING

Industry-sponsored funding administered through Kidney Health Australia

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: Grahame Elder

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All guideline writers are required to fill out a declaration of conflict of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Caring for Australasians with Renal Impairment Web site.

Print copies: Available from Caring for Australasians with Renal Impairment, Locked Bag 4001, Centre for Kidney Research, Westmead NSW, Australia 2145

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- The CARI guidelines. A guide for writers. Caring for Australasians with Renal Impairment. 2006 May. 6 p.

Electronic copies: Available from the Caring for Australasians with Renal Impairment (CARI) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 5, 2008. The information was verified by the guideline developer on June 11, 2008.

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